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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,958	04/10/2002	Y. Tom Tang	PF-0675 USN	6628
22428	7590	09/07/2004	EXAMINER	
FOLEY AND LARDNER			MARTINELL, JAMES	
SUITE 500			ART UNIT	
3000 K STREET NW			PAPER NUMBER	
WASHINGTON, DC 20007			1631	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,958

Applicant(s)

TANG ET AL.

Examiner

James Martinell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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Applicant's election with traverse of the requirement for restriction mailed May 10, 2004 in the reply filed on July 12, 2004 is acknowledged. The traversal is on the ground(s) that the application was filed under 35 U.S.C. § 371 and that therefore the polynucleotides and polypeptides should be rejoined. This is not found persuasive because the claimed polynucleotides and polypeptides do not in fact share a special technical feature as is evidenced by the citation herein below of prior art against some of the polynucleotide claims, which prior art would not be cited against a polypeptide claim. In addition, it is noted that searches for polypeptides and polynucleotides are not co-extensive and that searches of both create an undue burden on the resources of the USPTO.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 9, and 12-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 12, 2004.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Embedded hyperlink and/or other form of browser-executable code appear in at least the following locations:

- (a) page 15, lines 3 and 7.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3-8 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) Claims 3-8 are incomplete because they depend from non-elected claim 1.
- (b) Claims 4 and 10 are vague and indefinite because they claim more than the elected invention.
- (c) The recitation of "and RNA equivalent" (claim 10) is vague and indefinite because the instant application does not define the metes and bounds of what is meant by "equivalent".

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transformed unicellular host cells, does not reasonably provide enablement for the production of transformed organisms generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant application does not enable one of skill in the art to produce multicellular transgenic organisms without performing undue experimentation.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides of defined sequence, does not reasonably provide enablement for all "naturally occurring polynucleotide sequence[s] having at least 70% sequence identity" to SEQ ID NO: 35. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The CAFC in *In re Wands* (*In re Wands*, 8 USPQ2d 1400, Fed Cir. 1988) listed various factors to be considered in determining enablement. They include:

- (1) The quantity of experimentation necessary
- (2) The amount of direction or guidance presented
- (3) The presence or absence of working examples
- (4) The nature of the invention

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- (5) The state of the prior art
- (6) The relative skill of those in the art
- (7) The predictability of the art
- (8) The breadth of the claims

Each of these factors is discussed below.

*The quantity of experimentation necessary*

A large amount of experimentation is necessary because of the large number of genes and organisms that occur naturally.

*The amount of direction or guidance presented*

The application does not provide guidance as to which organisms are likely to harbor sequences that have at least 70% sequence identity to SEQ ID NO: 35.

*The presence or absence of working examples*

The instant application contains only one working example.

*The nature of the invention*

The nature of the invention is that of molecular genetics.

*The state of the prior art*

The prior art of record does not reveal any naturally occurring polynucleotides that have at least 70% sequence identity to SEQ ID NO: 35.

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*The relative skill of those in the art*

The relative skill of those in the art is high. The person with skill in the art most likely in possession of a Ph.D. degree and at least some post-doctoral research experience.

*The predictability of the art*

Genetics, in the sense of gene discovery, is an empirical art.

*The breadth of the claims*

The claims are very broad in that they embrace a large number of polynucleotides that exist in a large number of species of organisms.

After consideration of all of these factors, the claims are deemed not enabled for their full scope.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant application does not provide an adequate written description for all of the polynucleotides embraced by the claims (*i.e.*, all naturally occurring polynucleotides that are at least 70% identical to SEQ ID NO: 35).

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-8, 10, and 11 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose any connection between SEQ ID NO: 35 and any condition or disease. The long, ling list of maladies on page 33-34 of the instant application is not a disclosure of what SEQ ID NO: 35 is actually associated with. In *Brenner v. Manson*, Supreme Court of

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the U.S., 148 USPQ 689 (1966) the U.S. Supreme Court held that the claimed invention must have a real world use in its currently available (*i.e.* as of the effective filing date) form.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 11 is rejected under 35 U.S.C. 102(b) and(e) as being clearly anticipated by either one of Hudson (GenBank® Accession No. G25373, May 31, 1996, ENTREZ Release 24.0, August 15, 1996) or Cocks et al (U.S. Patent No. 6,607,879). Hudson et al discloses a polynucleotide that shares 113 nucleotides with SEQ ID NO: 35 (compare SEQ ID NO: 35, nucleotides 1793-1905 to the complement of Accession No. G25373, nucleotides 223-335). Cocks et al discloses a polynucleotide (*i.e.* SEQ ID NO: 209) that shares 109 nucleotides with SEQ ID NO: 35 (compare SEQ ID NO: 35, nucleotides 1834 to 1942 to Cocks et al SEQ ID NO: 209, nucleotides 1-109) and a polynucleotide (*i.e.* SEQ ID NO: 484) that shares 720 nucleotides with SEQ ID NO: 35 (compare SEQ ID NO: 35, nucleotides 1127-1846 to Cocks et al SEQ ID NO: 484, nucleotides 70-789). Thus, the polynucleotides of each of the references are embraced by the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719. The fax phone number for Examiner Martinell's desktop workstation is (571) 273-0719. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-

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mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

**PLEASE NOTE THE NEW FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1631**

9/1/04